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| EXAMINER |
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FLOOD, MICHELE C

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 01/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/606,314

Applicant(s)

Fike et al.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 4, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27, 36, 37, 39, 44-47, 70, 72, 92-95, and 100-103 is/are pending in the application.
- 4a) Of the above, claim(s) 100-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 36, 37, 39, 47, 70, 72, 92-95, and 103 is/are rejected.
- 7) ☒ Claim(s) 44-46 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on November 4, 2002. Acknowledgment is made of Applicant's cancellation of Claims 29-35, 40-43, 48-55, 60-69, 71 and 96-99, and newly submitted Claims 100-103.

Election/Restriction

Newly submitted Claims 100-102 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 100-102 are directed to "An agglomerated eukaryotic cell culture medium powder of claim 27 prepared by agglomerating a dry powder eukaryotic cell culture medium with an acid or base into said powder", which comprises an additional ingredient which was not included in the originally elected invention. For instance, the originally elected invention is directed to agglomerated cell culture medium powder agglomerated by agglomerating a dry powder eukaryotic cell culture medium with a solvent. Thus, Claims 100-102 constitute an additional invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 100-102 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 27, 36, 37, 39, 44-47, 70, 72, 92-95 and 103 are under examination.

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Priority

Please note that in the previous "Office Action Summary" - Form PTO-326, the Office inadvertently indicated in item No. 15) that "Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § § 120 and/or 121". Note that on the present "Office Action Summary" (attached hereto) the Office has correctly identify and indicated in item No. 14) Acknowledgment of Applicant's claims for domestic priority under 35 U.S.C. § 119 (c). Accordingly, Applicant is advised to correct Form PTO-326 of Paper No. 15.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Claim Objections

Claim 70 is objected to because of the following informalities: Claim 70, line 3 recites "100-104"; however, no Claim 104 is pending in the present application. It appears that the recitation is an apparent typographical error. Appropriate correction is required. Newly applied as necessitated by amendment.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 27, 36, 37, 39, 47, 92-95 and 103 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Peebles (A) and Getler et al. (N), as evidenced by the teachings of Ellington et al. (B).

Applicant claims an agglomerated eukaryotic cell culture medium powder prepared by agglomerating a dry powder eukaryotic cell culture medium with a solvent. Applicant further claims the medium powder of claim 27, wherein the agglomerated eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated. Applicant further claims the medium powder of any of claims 93-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder. Applicant further claims the agglomerated eukaryotic cell culture medium powder of any one of claims 27, 37, or 39, wherein said solvent is water, serum, aqueous acid or base.

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Applicant argues that the amendments to the claims overcome the prior art. However this is not persuasive because Peebles and Getler teach the claimed invention, as evidenced by the teachings of Ellington. Firstly, Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture. See Column 2, lines 13-70. The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting. See claims and Column 9, lines 46-54. Secondly, Getler teaches agglomerated milk products and milk-like products which are made in a two-stage agglomeration process comprising spray drying a pre-agglomerated concentrated premix by return of fine particles to an atomizer and, in a subsequent step, post-agglomeration by wetting and drying in a fluidized bed. The agglomerated dried products taught by Getler comprise the following ingredients: whey protein concentrates (see page 1, lines 11-14); and a fat component mixed with water, vitamins, and with raw materials in powder form, i.e., casein, whey, skim milk, malto dextrine, etc. (see page 6, line 36 to page 7, lines 1-2). In Example 3, Getler teaches an agglomerated nutritive medium powder which exhibits reduced dusting and rapid dissolution.

Given the broadest breadth of interpretation of the claims, the agglomerated powders taught by Peebles and Getler are read as “an agglomerated eukaryotic cell culture medium powder”, “an agglomerated eukaryotic cell culture medium supplement powder”, and “an agglomerated eukaryotic cell culture medium subgroup powder” because the products can be

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used in the culturing of eukaryotic cells (as evidenced by the teachings of Ellington) and can be grouped within the scope of the various media subgroupings as described by Applicant on page 6, lines 13-28 and page 7, wherein dried milk can be considered as an animal extract of mammalian cells containing fats, proteins and vitamins, etc., and whey protein concentrates can be considered as a plant cell. Applicant further argues that "Dry milk products are inappropriate for the culture of eukaryotic cells." However, Applicant's argument ^{is} unpersuasive because Ellington clearly teaches that cell culture media comprising milk products, e.g. skim milk, is appropriate in the culturing of eukaryotic cells. See Column 5, lines 29-44.

Each of the references of Peebles and Getler are deemed to anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 36, 37, 39, 47, 70, 72 and 92-95 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peebles (A) and Getler et al. (N) in view of DiSorbo et al. (AG2).

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Applicant's claimed invention of Claims 27, 36, 37, 39, 92-95 and 103 was set forth above. Applicant further claims a kit for use in the cultivation of a cell, said kit comprising one or more containers wherein a first container contains the powder of an one of recited claims. Applicant further claims a kit of claim 70, further comprising one or more additional containers containing one or more solvents.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary references of Peebles and Getler were relied upon for the reasons set forth immediately above. Neither Peebles nor Getler teach a kit for use in the cultivation of a cell, therefore the secondary reference of DiSorbo was relied upon because DiSorbo teaches a kit comprising one or more containers containing nutritive media, media supplements and media subgroups and one or more containers containing solvents, which can be used to formulate a medium to support the in vitro cultivation of a cell, e.g., bacterial cell, a fungal cell, a plant cell, or an animal cell.

Thus, with Peebles and Getler providing the claimed agglomerated eukaryotic cell culture medium powders, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to incorporate the referenced powders in the making of a kit by containing the referenced powders in a first container and providing one or more additional containers containing one or more solvents because DiSorbo teaches a kit comprising one or more containers containing nutritive media, media supplements and media subgroups and one or more containers containing solvents, which can be used to formulate a medium to support the in vitro cultivation of a cell, e.g., bacterial cell, a fungal cell, a plant cell, or an animal cell. One of ordinary skill in the art would have been motivated to combine the instantly claimed materials in the making of a kit for use in the cultivation of a cell because one would have had a reasonable expectation of success that the making of the claimed kit as a product of sale would be useful and convenient to the biomedical community because DiSorbo relates the reduced cost that his invention provides for the preparation of cell culture media, since the media subgroupings can be easily stored and admixed to make custom media, when needed. Therefore, the invention as a whole was clearly prima facie obvious in the absence to the contrary.

Allowable Subject Matter

2. Claims 44-46 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

January 9, 2003



**CHRISTOPHER R. TATE
PRIMARY EXAMINER**